Remarks

Application Status and Disposition of Claims

In the Final Office Action, the Office indicated that claims 1-34 are pending. With the present amendment, claims 1 and 12 are amended and claims 4, 5, 32, and 33 are canceled. Claims 19-24 and 34 have been withdrawn from consideration as directed to a non-elected invention.

Applicants note that the withdrawn claims are kept pending, subject to possible rejoinder.

Claim Rejections – Obviousness-Type Double Patenting

The Office Action maintains the rejection of claims 1-18 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 6, 12-17 of U.S. Patent No. 6,268,119 (hereinafter "SUMITA") in view of Oka et al. (U.S. Patent No. 5,298,165, hereinafter "OKA 1"), Oka et al. (U.S. Patent Application Publication No. 2004/0251195, hereinafter "OKA 2"), Fukuda et al. (WO 02/087660, hereinafter "FUKUDA"), and Rubenstein et al. (Proc. Nat'l Acad. Sci. USA, 1995, 92:10119-10112, hereinafter "RUBENSTEIN").

Applicants respectfully disagree with the Office for the reasons set forth previously in prior responses. For brevity, the content of those responses is not restated here, but is expressly incorporated by reference as though set forth in full herein. Applicants maintain that the Examiner's rejection is legally incorrect and request its withdrawal.

Claim Rejections – 35 U.S.C. § 103

The Office Action maintains the rejection of claims 1-17 and 30-33 under 35 U.S.C. § 103(a) as being obvious over SUMITA in view of OKA 1, OKA 2, FUKUDA, and RUBENSTEIN. The Office Action also rejects claims 1-18 and 30-33 under 35 U.S.C. § 103(a) as being obvious over SUMITA in view of OKA 1, OKA 2, FUKUDA, RUBENSTEIN, and further in view of Tanaka et al. (U.S. Patent No. 6,048,464, hereinafter "TANAKA").

Applicants respectfully disagree with the basis for the rejections for the reasons set forth fully in the prior responses. Applicants also respectfully note that it is clear from the Final Office Action that the Examiner has misinterpreted the claimed invention, and that that misinterpretation is at least one reason for the improper rejection.

The present claims recite that "the layer rich in unnecessary cells is *first* introduced into the above-described filter device, and the layer rich in nucleated cells is *then* introduced therein, so as to discharge the unnecessary cells remaining in the above-described filter device while capturing the nucleated cells by the above-described filter material, and a recovery solution is *then* introduced into the above-described filter device, so as to recover the nucleated cells captured by the above-described filter material." (Emphasis added.) Thus, claim 1 recites an order of 1) unnecessary cells (i.e., erythrocytes), 2) nucleated cells (i.e., monocytes, which may be found in a buffy coat), and then 3) recovery solution (e.g., plasma). The Examiner asserts that the art discloses an order of: 1) erythrocytes, 2) plasma, then 3) monocytes (buffy coat).

The fact that the Examiner has misinterpreted the claims is clear from the Final Office Action. On page 17, in explaining why Applicants' arguments were not persuasive, the Examiner states:

> The instant claims are drawn to a method of preparing a nucleated cell concentrate by first separating a cell-containing solution into a layer rich in nucleated cells, a nucleated cell-diluted layer, and a layer rich in unnecessary cells and introducing these layers into a filter such that **[1]** the layer rich in unnecessary cells is introduced first, followed by **[2]** the nucleated cell-diluted layer and then **[3]** the layer rich in nucleated cells (see the instant claims 1 and 7).

(Page 17, second full paragraph, reference numerals added.) Thus, the Examiner states that Applicants' claim is in the order of 1) unnecessary cells, 2) nucleated cell-diluted layer (i.e., plasma), and then 3) layer rich in nucleated cells. This is clearly incorrect.

Based on the Examiner's misinterpretation of the claim, and the reliance on the art based on this misinterpretation, the rejection is improper and should be withdrawn. Additionally, because it is clear the prior rejection was also based on an incorrect claim

interpretation, finality is improper and should be withdrawn. Applicants submit that the rejection should also be withdrawn for the following additional reasons.

The present invention includes the feature that a cell-containing solution is separated into a layer that is rich in nucleated cells and a layer that is rich in unnecessary cells. The layer rich in unnecessary cells is first introduced into a filter device, and then the layer rich in nucleated cells is introduced. The primary reference, Sumita et al., fails to disclose this feature. The Examiner relies on Fukuda et al. (U.S. Application Publication No. 2004/0200775) and Oka et al. (U.S. Application Publication 2004/0251195) for this missing feature, and asserts that it would be obvious to combine Sumita et al. with Fukuda et al. and Oka et al. Applicants disagree.

Oka et al. relates to a blood processing filter for removing leukocytes. Oka et al. discloses generally that whole blood can be separated into several blood components by centrifugation, and then removal of leukocytes can be performed. Oka et al. does not disclose the feature and advantageous effect that by performing the steps in the recited manner, nucleated cells and unnecessary cells can be efficiently separated from each other.

Fukuda et al. discloses that, before introduction of blood into a leukocyte removal filter, a blood concentration gradient is formed in a blood pooling unit and the blood is filtered. According to Fukuda et al.'s method, leukocytes can be efficiently removed and platelets can be recovered at a high recovery rate.

Thus, both Oka et al. and Fukuda et al. relate to systems for *removing cells* (namely, leukocytes), while the present invention relates to a system for *recovering cells*. In Fukuda et al., the blood cells are separated from the heavy cells to light cells by specific gravity (namely, erythrocytes → granulocytes/monocytes → lymphocytes → platelets/plasma), and the cells are introduced into the filter in this order. Importantly, however, the object and effect of Fukuda et al., i.e., efficient leukocyte *removal* and high recovery rate of platelets, is different from that of the present invention. Applicants respectfully submit that Fukuda et al. does not teach or suggest the present invention.

Applicants also respectfully submit that the unexpected results observed with the present invention weigh in favor of nonobviousness. As demonstrated in Examples 1 and 2 and in Comparative Example 1 of the specification, the volume of erythrocytes can be reduced and mononuclear cell recovery rate increased to an expected level by first introducing the layer rich in unnecessary cells into a filter and then introducing the layer rich in nucleated cells into the filter. As noted above, Oka et al. and Fukuda et al. are note concerned with cell recovery, and so provide no suggestion at all about the increased recovery achieved by the specifically recited steps of the present invention. Applicants respectfully submit that the unexpected results obtained cannot have been predicted based on the teachings of Oka et al., Fukuda et al., or Sumita et al.

Conclusion

In view of the foregoing remarks and amendments, Applicants respectfully request withdrawal of the rejections for obviousness.

Applicants hereby authorize the charging of any required fees necessary for consideration of this paper to Deposit Account No. 19-0089. Any comments or questions concerning this application can be directed to the undersigned at the telephone number given below.

Respectfully submitted,
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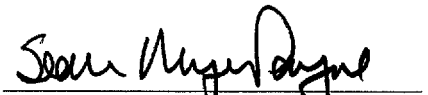

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